TSCA HEALTH & SAFETY STUDY COVER SHEET

MR 280105

TSCA CBI STATUS: NONE

8EHQ-1004-15757

1.0 SUBMISSION TYPE

☐ 8(d) **XX 8(e)** ☐ FYI ☐ 4 ☐ OTHER: Specify_____

XX- Initial Submission - Follow-up Submission ☐ Final Report Submission

Previous EPA Submission Number or Title if update or follow-up: Docket Number, if any: #

☐ continuation sheet attached

2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI) X- YES ☐ NO	**2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID** **7106 4575 1292 0338 1026** L-04-2-1	**2.3 FOR EPA USE ONLY**

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY

Reported Chemical Name (specify nomenclature if other than CAS name):

CAS# : 3173-53-3 Cyclohexylisocyanate

Purity ___%

X- Single Ingredient

☐ Commercial/Tech Grade

☐ Mixture *Trade Name Cyclohexylisocyanate* *Common Name:*

CAS Number	*NAME*	*% WEIGHT*
Other chemical(s) present in tested mixture		

☐ continuation sheet attached

4.0 REPORT/STUDY TITLE

In Vitro chromosome Aberration Test with Chinese Hamster V79 Cells – T5073221

☐ continuation sheet attached

5.1 STUDY/TSCATS INDEXING TERMS

[CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE):_____ ENVIRONMENTAL FATE (EF):_____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: Vitro	SUBJECT ORGANISM (HE, EE) HAMS	ROUTE OF EXPOSURE (HE only):__	VEHICLE OF EXPOSURE (HE only)_
Other:	*Other:*	*Other:*	*Other:*

6.0 REPORT/STUDY INFORMATION ☐ Study is GLP

Laboratory Bayer Healthcare AG Toxicology Report/Study Date: 10/8/2004

Source of Data/Study Sponsor (if different than submitter) Lanxess Corporation Number of pages _-

☐ continuation sheet attached

7.0 SUBMITTER INFORMATION

Susan VanVolkenburg
Manager, Product Safety & Regulatory Affairs
Lanxess Corporation
100 Bayer Road
Pittsburgh, PA 15205 **412-777-4185**

CONTAINS NO CBI

Technical Contact: SAME AS ABOVE Phone: ( )_____

☐ continuation sheet attached

8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS

This compound is a commercial product.

☐ continuation sheet attached

8EHQ-04-15757

Submitter Signature: Susan VanVolkenburg **Date:** 10/8/2004

Continuation of 2.1

Reporting is based on the following summary results.

SUMMARY:

The clastogenic potential of Cyclohexylisocyanat was evaluated in a chromosome aberration test in vitro. Initially Chinese hamster V79 cells were exposed in the absence of S9 mix for 4 hours to concentrations of 1, 2, 4, 6, and 8 µg/ml of Cyclohexylisocyanat. Cultures of all concentrations were harvested 18 hours after the beginning of the treatment. In addition, cells treated with 4, 6, and 8 µg/ml were harvested 30 hours after the beginning of the treatment. In the presence of S9 mix cells were exposed for to concentrations of 4, 8, 18, 22, and 26 µg/ml of Cyclohexylisocyanat. Cultures of all concentrations were harvested 18 hours after the beginning of the treatment. In addition, cells treated with 18, 22 and 26 µg/ml were harvested 30 hours after the beginning of the treatment. Based on their cytotoxicity concentrations were selected for reading of metaphases.

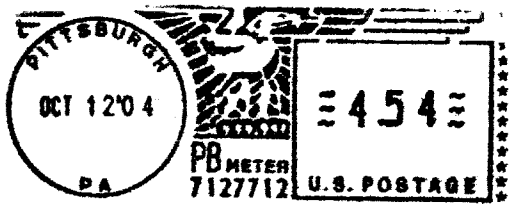
Without S9 mix cytotoxic effects were observed at 2µg/ml and above. With S9 mix cytotoxic effects were observed at 4 µg/ml and above. Precipitation in the medium was not observed.

Therefore, concentrations of 1, 2 and 4 µg/ml Cyclohexylisocyanat were chosen for reading in the absence of S9 mix. In the presence of S9 mix 4, 8 and 18 µg/ml of Cyclohexylisocyanat were employed. All of these cultures harvested 18 hours after the beginning of the treatment were included. In addition, cultures treated in the absence of S9 mix with 4 µg/ml and harvested 30 hours after the beginning of the treatment were used. The same was true for cultures treated in the presence of S9 mix with 18 µg/ml.

In the absence of S9 mix cultures treated with Cyclohexylisocyanat showed at 4 µg/ml statistically significant increases for the numbers of aberrant metaphases which were of questionable biological relevance. However, in the presence of S9 mix cultures treated with Cyclohexylisocyanat showed biologically relevant and statistically significant increased numbers of aberrant metaphases at 18 µg/ml.

The positive controls mitomycin C and cyclophosphamide induced clastogenic effects and demonstrated the sensitivity of the test system and the activity of the used S9 mix.

Based on this test, Cyclohexylisocyanat is considered to be clastogenic for mammalian cells in vitro, at least with S9 mix.


PITTSBURGH
OCT 12'04
PA
PB METER
7127712
454
U.S. POSTAGE


TOP OF ENVELOPE
TO THE RIGHT OF RETURN ADDRESS
FOLD AT DOTTED LINE
CERTIFIED MAIL
7106 4575 1292 0338 1026
RETURN RECEIPT REQUESTED